



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/909,879	08/12/97	PRIEELS J	04012.0188

HM21/0810
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EXAMINER
SMITH, L

ART UNIT	PAPER NUMBER
1648	28 29

DATE MAILED: 08/10/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/909,879

Applicant(s)
Prieels et al

Examiner
Lynette R. F. Smith

Group Art Unit
1648



☒ Responsive to communication(s) filed on May 22, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19-32 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/356,372.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1648

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The examiner acknowledges the amendment and the declaration of Dr. Voss.

4. Claims 1-18 have been canceled and claims 19-32 are pending and under consideration.

5. Applicant's arguments filed 5/22/98 have been fully considered but they are not persuasive. The rejection of claims 19-32 under 35 U.S.C. 112 first paragraph, because the specification while being enabling for claims limited to a vaccine composition comprising antigens from Herpes Simplex Virus, CS protein of plasmodia species and Hepatitis B surface antigen in combination with adjuvants QS-21 and 3-DMPL and methods of synergistically enhancing the immune response and stimulating the production of gamma interferon, does not reasonably provide enablement for a vaccine comprising antigens from HIV or FIV, is maintained for reasons set forth in the previous office action.

Applicant urges the declaration of Dr. Voss traverses the rejection because the declaration establishes that the rhesus monkey model is an acceptable model, phase I clinical trials have established the safety and immunogenicity of the vaccine, the invention stimulates a very strong cytokine response and those of ordinary skill in the art would recognize that high CTL levels are indicative of anti-HIV therapy and are the focus of vaccine research.

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It is the examiner's position that after review of the information submitted by Dr. Voss, it appears that the following points should be noted. The declaration of Dr. Voss:

a) does not address FIV antigens or vaccines and whether or not the claimed adjuvants are effective in feline immunodeficiency vaccine preparations

b) does not establish the ability of CTL responses to HIV, to reduce viral burden or viral load or that CTL responses generated in response to vaccine administration generated protection

c) does not establish the correlation between HIV-specific CTL responses and slowing of progression to AIDS. Indeed Dr. Voss states that the assays designed to detect HIV-specific CTL responses did not generate any interpretable data.

D) does not establish that a synergistic response was obtained with HIV or FIV and the QS-21 and 3-D MPL adjuvants in the generation of gamma interferon and

e) the claims are drawn to a vaccine comprising HIV or FIV antigens which stimulate gamma interferon and cytolytic T cell responses. The declaration does not establish that T cell responses were generated to HIV and FIV nor the identity of the cell type involved.

In view of all of the information submitted and in view of the specification the rejection is being maintained.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1648

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lynette F. Smith whose telephone number is (703) 308-3909.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SMITH/lfs *LFS*
August 6, 1998

L. F. Smith
LYNETTE F. SMITH
PRIMARY EXAMINER
GROUP 1800